

SPL ER/DL Team

Jun 22, 2011

Minutes

Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Chair for this meeting: Michelle Halliez

To do:

- Pat to send question #3 below to Paul Loebach.
- Pat to contact Paul / Leyla and ask them to attend a future meeting in August to discuss the new NDC directory and old NDC directory. Set up for August 17.
- Pat to send out call for questions for this meeting.

NDC Directory Issues:

1. NDC Directory: Multiple start marketing dates for the same package code. Package code is identical except for the market starts dates. Kathleen Lins/ Erika Morgan
 - Example: 0409-1985-01
 - 4/25/2011
 - 5/26/2011
 - Hospira has seen multiple examples of this duplication.
 - Question for DRLS
2. Issue: the complete NDC is on the far right. Can see it...but it is hard to see.
3. NDC Directory: I would like to discuss the NEW/OLD NDC Directory. Are the NDC Numbers that appear only in the OLD system still considered active from a CMS perspective? What about for Imports – is the OLD Directory still a viable resource when importing a drug product that does not appear in the NEW Directory yet? Kathleen Lins/ Erika Morgan
 - Old NDC: Is CMS going to consider the NDCs in the old NDC as active products?
 - Also....can the import group see the old system?
 - Pat to ask DRLS
4. NDC Directory: Suggestion – is there a way to get a screen print so that we can forward it to
 - They used to be able to take a screen print or download to an excel
 - Sponsors store it with their submission stuff to confirm that it was drug listed.
 - Now the screen is too wide to print out.
5. Now that the new NDC Directory has rolled out, will we be having a discussion regarding the changes. One area of concern is that the inner NDC numbers will not appear. We understood that this was needed by the CMS group for reimbursement [Ruth Kirkner]

"The NDC Directory does not contain all listed drugs. It does not include animal drugs, blood products, or human drugs that are not in final marketed form, such as active pharmaceutical ingredients, or drugs that are marketed solely as part of a kit or combination product or inner layer of a multi-level packaged product."

- Question for DRLS

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Other questions for future discussion:

6. Validation errors, that have been resolved by manually loading a new SPL file, are coming back multiple times. It appears that the validation routine is They are going to SPL group to see how they can fix the problem permanently.
 - SPL group says that it may be a vendor problem / software problem.
 - Sometimes it takes several times to fix the problem.
 - People will let us know if they get more information and/or resolution on this.

7. In a situation where a CBE is changed to a PAS, and the CBE version of the circular is pulled back and replaced with the previous version while the PAS is pending, what is the process for replacing the eListed SPL with the previous version? Can we revert back to the previous SPL version we already submitted? Or do we need to resubmit that SPL as a new version with new version number and rootID? Also, is there a defined period of time after a CBE is submitted that FDA has to tell a sponsor to change a CBE to a PAS? Soslow, Amy
 - Jackie: To their knowledge, they need to update the version and GUID....but leave the rest of the document the same.
 - Is there a time period within which the FDA needs to respond? Suggestion – call back

8. Error message about mismatched labeler codes – Pat
"labeler in the data elements section does not appear to be consistent with label".
Response from Dragan: It sounds like your Labeler identified in the Labeler field does not match the Labeler code you for the NDC Labeler Code for Packages or the Label images.
 - Background: Originally this was files in paper and there was another name provided in the "doing business as" field. This had been drug listed successfully several times successfully. All the electronic files are consistent as "Baker". Acme was the DBA company in the paper 2656 form.
 - DER form....company "Baker"
 - SPL drug listing "Baker"
 - Labeler code "Baker"
 - Artwork has "Acme"
 - Resolution was a manual override. Suggestion to go back to Lonnie and ask him how to fix this permanently.
 - Example of drug listing with company doing-business-as (DBA). There are 866 labelers with DBA in the company name in the access database – some multiples
 - <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?ndc=0615-7568&start=1>

9. DIA session: Future of SPL- What's next – in October 11-12, 2011. Bethesda, MD, Marriott
 - a. Dragan will chair this session.
 - b. See DIA web site for list of topics
 - c. <http://www.diahome.org/DIAHome/Education/FindEducationalOffering.aspx?roi=ec4-14427260786-11923696-5ae4484b5acb978d3f573280c2fb1272&productID=27298&eventType=Meeting>

Next meeting is August 3rd.

The meeting ended here.

10. Please discuss the suggestion of including lot distribution data in the SPL file. How can this be accomplished? Will an SPL file have to be updated at each lot release? – Jean
11. We currently use the campus approach for our manufacturing facility at our corporate center. We are currently trying to assess the possibility (and value) of subdividing the campus into smaller sub-sites, based on manufacturing functional -- ie API, dry products, and parenteral. - Pat
12. Are companies adding alternate testing sites for drug substances to the Labeler and Manufacturer Information section of the SPL or just adding the API supplier to the Labeler and Manufacturer Information section of the SPL? – Kathleen
13. Has anyone received the following packaging validation error even though there are no drug listing differences in the SPL since the last posted SPL: "If the NDC Package Code has been previously submitted, then the package form code and quantity value and unit must be the same as in the most recent submission for this NDC code". – Amy
14. In a situation where a CBE is changed to a PAS, and the CBE version of the circular is pulled back and replaced with the previous version while the PAS is pending, what is the process for replacing the eListed SPL with the previous version? Can we revert back to the previous SPL version we already submitted? Or do we need to resubmit that SPL as a new version with new version number and rootID? Also, is there a defined period of time after a CBE is submitted that FDA has to tell a sponsor to change a CBE to a PAS? - Amy
15. There are two examples of Drug Listing Data for products that use the term "equivalent to" and want to see how other companies are portraying this information. - Kathleen
Have seen similar "equivalent to" information in labels and see other companies portray this information different than our company does:
 - a. Example 1: Description section states, "Each mL contains 118 mcg of dexmedetomidine hydrochloride equivalent to 100 mcg of dexmedetomidine". Drug Listing Data looks like this:

Active Ingredient/Active Moiety:
Ingredient Name: **DEXMEDETOMIDINE HYDROCHLORIDE** (Dexmedetomidine)
Basis of Strength: Dexmedetomidine
Strength: 100 ug in 1 mL

In this case does it matter whether you use 118 mcg/mL and choose dexmedetomidine hydrochloride as the basis of strength?
 - b. Example 2: Description section states, "The vials contain sterile vancomycin hydrochloride equivalent to either 500 mg or 1 g vancomycin activity.". Drug Listing Data looks like this

Active Ingredient/Active Moiety:

Ingredient Name: **VANCOMYCIN HYDROCHLORIDE** (VANCOMYCIN)

Basis of Strength: VANCOMYCIN

Strength: 500 mg in 10 mL or 1 g in 20 mL

In this case does it matter whether you use 118 mcg/mL and choose dexmedetomidine hydrochloride as the basis of strength?

16. My boss is expressing concern over these new document types (I thought I was going to have to give her CPR). Lonnie has requested that we switch our Kogenate antihemophilic factor (recombinant) to the plasma derived template. The templates listed below will be available in the newest i4i release set for June 5th. Please see her comments below.

New SPL Document Types

- CELLULAR THERAPY
- CELLULAR THERAPY with highlights
- PLASMA DERIVATIVE
- PLASMA DERIVATIVE with highlights
- LICENSED VACCINE BULK INTERMEDIATE LABEL
- LICENSE BLOOD INTERMEDIATES/PASTE LABEL
- STANDARDIZED ALLERGENIC
- STANDARDIZED ALLERGENIC with highlights

"To have any classification or categorization of recombinant products as plasma-derived products without a recombinant distinction can be quite problematic. As the SPL is posted publicly, can be downloaded by anyone with access to the internet, yet can easily misinterpret the evolving and complex data associated with these files, it is of great concern that someone could misunderstand that this recombinant product is somehow also viewed as a plasma-derived product. This immediately brings to mind the valid concerns and problems of plasma-derived products during the 1990s where some used plasma containing infectious disease elements before certain infectious diseases were better understood. There are countries that depend upon the FDA-associated documentation of US approved biologics, yet are only beginning to introduce recombinant products into their countries.

The below statement is from the FDA - CBER website on a project page "Towards More Effective Treatment for Blood Clotting Disorders: Pharmacogenetics of von Willebrand Factor (vWF) and Related Proteins":

<http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/BiologicsResearchAreas/ucm127059.htm>

The Division of Hematology is responsible for the evaluation of biologic products related to blood. Among these products are recombinant coagulation factors that are substitutes for their plasma-derived counterparts.

If it is a matter of naming a document type or template, please consider adding "recombinant" or changing to "factors". Please do not limit the name to 'plasma derived'."

Followup with outcomes:

- Paula Finn: problems with establishment information for "campuses" and French.